

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 26, 28 and 29 are currently amended. Upon entry of this response, which introduces no impermissible new matter, claims 1-33 will be pending and claims 1-25 and 31-33 will be withdrawn.

Claim Rejections under 35 U.S.C. § 112

Claim 30 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In response, without agreeing or acquiescing to the rejection, Applicants have amended claims 28 and 29 so that claim 30 no longer depends from another multiple dependent claim. Accordingly, Applicants request that the rejection be withdrawn and claim 30 be allowed.

Claim Rejections under 35 U.S.C. § 102

Claims 26-30 were rejected as anticipated by U.S. Patent No. 4,916,056 ("Brown"). In response, without agreeing or acquiescing to the rejection, Applicants have amended independent claim 26. Further, Applicants respectfully traverse the rejection for the reasons set forth below.

Independent claim 26 is directed to a "flow-through assay apparatus for detecting an analyte" which comprises "(A) a solid-phase support onto which a capture reagent that specifically binds to the analyte has been immobilized and (B) a porous material impregnated with a labeled reagent containing a ligand that specifically binds to the analyte, *wherein the porous material is contained in an adaptor that (i) is provided in an upper layer of the solid-phase support and (ii) is contacted with the solid-phase support and wherein the porous material is configured such that the analyte and the labeled reagent are contacted and mixed within the porous material.*"

Accordingly, as claimed in claim 26, the adaptor provided in an upper layer of the solid-phase support is in contact with the solid-phase support, and the porous material is configured such that the analyte and the labeled reagent are contacted and mixed within the porous material.

Brown discloses a flow-through assay device comprising the porous prefilter 22d and the reaction matrix 12. Thus, the examiner asserts that the claims are anticipated by the flow-through assay device of Brown.

The examiner apparently believes that the presently recited porous material corresponds to a prefilter 22d of Brown's flow-through assay. Yet, the porous material, as recited in claim 26, is impregnated with a labeled reagent containing a ligand that specifically binds to the analyte. Additionally, the claimed porous material is in contact with and mixed with the analyte and the labeled reagent.

In contrast, Brown does not disclose that the prefilter 22d comprises labeled reagents containing ligands which specifically bind to an analyte. Additionally, the prefilter 22d does not play a role for contacting and mixing the analyte and the labeled reagent. Instead, for the function of the prefilter 22d, Brown discloses the following:

"the means 22 can perform such functions as a reservoir to retain sample or slow the passage of sample or reagents to the reaction matrix 12; as a vehicle to retain reagents, e.g., lyophilized reagents, to be used in an assay; and as a "prefilter" to remove extraneous articulate matter in a sample, or, for example, to separate and to hold blood cells from a whole blood sample while allowing plasma to pass through." See, column 8, lines 13-20.

Therefore, the porous material as claimed in claim 26 and the prefilter 22d of Brown have different structures and different functions. Accordingly, Applicants respectfully request that the rejection be withdrawn and independent claim 26 be allowed. Further, claims 27-30 depend from claim 26 and should be allowed for the reasons set forth above.

If this rejection of the claims is maintained, the examiner is respectfully requested to point out where the above-mentioned features are disclosed in Brown.

Claim Rejections under 35 U.S.C. § 103

Claims 26-30 were rejected over WO 03/016902 ("Cole 1") in view of U.S. Patent No. 5,141,850 ("Cole 2"). In response, without agreeing or acquiescing to the rejection, Applicants have amended independent claim 26. Further, Applicants respectfully traverse the rejection for the reasons set forth below.

Independent claim 26 is directed to a "flow-through assay apparatus for detecting an analyte" which comprises "(A) a solid-phase support onto which a capture reagent that specifically binds to the analyte has been immobilized and (B) a porous material impregnated with a labeled reagent containing a ligand that specifically binds to the analyte, *wherein the porous material is contained in an adaptor that (i) is provided in an upper layer of the solid-phase support and (ii) is contacted with the solid-phase support and wherein the porous material is configured such that the analyte and the labeled reagent are contacted and mixed within the porous material.*"

Accordingly, as claimed in claim 26, the adaptor provided in an upper layer of the solid-phase support is in contact with the solid-phase support, and the porous material is configured such that the analyte and the labeled reagent are contacted and mixed within the porous material.

Cole 1 discloses a flow-through apparatus comprising a first member comprising a first, porous, reaction membrane to which is bound to a capture analyte for binding to a reagent to be detected; and a chamber spaced above the first member having side walls and a base defined by a second membrane. *See Fig. 1.* Additionally, Cole 1 discloses that a sample and labeled reagent are added to the chamber and allowed to flow through to the reaction chamber. Cole 2 teaches that the labeled reagent may be immobilized in a porous material.

Page 12 of Cole 1 describes mixing the sample to be analyzed and the labeled reagent in the liquid state in the pre-incubation chamber. In the mixing step, the pre-incubation chamber does not contact with the membrane carrying the capture analyte. Therefore, the mixture of the sample to be analyzed and the labeled reagent cannot transfer into the membrane.

After incubating for a certain period of time, the pre-incubation chamber is forced downward. Consequently, the filter at the base of the incubation chamber (the mixture of the sample to be analyzed and the labeled reagent cannot pass through the filter by gravity) can contact the membrane carrying the capture analyte in order that the mixture of the sample to be analyzed and the labeled reagent can transfer from the incubation chamber into the membrane carrying the capture analyte.

Thus, the invention described in Cole 1 comprises the steps of: waiting for a certain period to create the complexes of the reagent to be detected and the labeled reagent in the pre-incubation chamber; and pushing the incubation chamber down to the membrane carrying the capture analyte in order to transfer the complexes to the membrane. These steps are not necessary for the device recited in claim 26.

In Cole 1, the reagent to be detected and the labeled reagent are pre-incubated in the pre-incubation chamber to create the complexes thereof. Moreover, if the pre-incubation chamber and the membrane carrying the capture analyte are in contact from the start in the apparatus of Cole, then the formation efficiency of the capture analyte- the reagent to be detected-the labeled reagent complex may be decreased, because the reagent to be detected and the labeled reagent can transfer from the pre-incubation chamber to the membrane before the complexes thereof are sufficiently created.

Pursuant to claim 26, by contrast, the labeled reagent is impregnated in the porous material. Namely, when the liquid sample containing the reagent to be detected is applied into the adaptor, the liquid sample

seeps into the porous material and does not transfer to the membrane immediately. That is, the reagent to be detected and the labeled reagent are complexed in the porous material, and subsequently the complex transfers to the membrane. Therefore, instead of the pre-incubation step which requires a certain period of time as disclosed in Cole 1, the claimed apparatus uses porous material impregnated with the labeled reagent.

Cole 2 fails to cure the deficiencies of Cole 1. Cole 2 discloses that a labeled component and a capturable component are localized at the labeling zone and the detection zone on the same dipstick, respectively. *See* Col. 5, lines 8-21. In Cole 2, the liquid analyte can transfer to the labeling zone and can be mixed with the labeled component contained in the labeling zone. In that case, the liquid analyte may react with the enriched labeled component for the initial period of time. However, the amounts of the labeled component which can react with the liquid analyte may lessen gradually as the reaction advances. Additionally, when the liquid analyte transfers from the labeling zone to the detection zone, many unreacted labeled components may also transfer to the detection zone with the liquid analyte. Therefore, the liquid analyte transferring later may react with the labeled components whose concentration may be lower than that of the labeled components reacted with the liquid analyte transferring at the beginning. The concentration gradient between the liquid analyte and the labeled components may cause a reaction efficiency of the analyte and the labeled components to decrease.

In contrast, applying the analyte into the adaptor which contains the labeled components, as claimed in claim 26, avoids the concentration gradient between the analyte and the labeled components. As a result, the analyte can effectively, sensitively, and specifically react with the labeled components.

Accordingly, the combination of Cole 1 and Cole 2 fail to disclose each and every limitation of independent claim 26. Claims 27-30 depend from independent claim 26 and should be allowed for the reasons set forth above without regard to further patentable limitations contained therein.

If this rejection of the claims is maintained, the examiner is respectfully requested to point out where the above-mentioned features are disclosed in the cited references.

CONCLUSION

Applicants submit that this application is in condition for allowance, and they request an early indication to that effect. Examiner Nguyen is invited to contact the undersigned directly, should he feel that any issue warrants further consideration.

The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 C.F.R. §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper

payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of submitted papers, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of the relevant fee(s) from the deposit account.

Respectfully submitted,

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By Stephen A. Bent

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5404
Facsimile: (202) 672-5399

Stephen A. Bent
Attorney for Applicant
Registration No. 29,768